

Proposal to Eliminate the Use of an Alternate Label for Perfusion Machines and Require the Standardized OPTN Label

Fall 2011

OPO Committee

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Overview

- Current policy allows members to use an “alternate” label and members create their own alternate labels resulting in inconsistent labeling practices.
- Proposed policy changes:
 - Eliminate the use of alternate shipping labels on mechanical preservation machines
 - Require OPOs to use a new standardized label that will be part of the current color-coded labeling system distributed by the OPTN contractor

Policies Affected & Rationale

- Policy 5.1.3 Mechanical Preservation Machine and Policy 5.3 External Labeling Requirements
- Living Donor policy has been written and does not allow for the use of an alternate label.
- This proposed change will:
 - Make labeling consistent throughout the country for all kidneys transported on a perfusion machine
 - Align living donor and deceased donor policy
 - Reduce the chance of error and increase patient safety

Background Information

- Out of 4,449 kidneys placed on perfusion machines, 2,779 were transported to a different location.
- From January 2011 to June 2011, one out of 17 reported packaging and labeling errors occurred due to inaccurate labeling of a perfusion machine.
- These changes will not require programming in UNetSM.

UNOS ID _____

ORIGINATING OPO _____

() _____

ORIGINATING OPO TELEPHONE # _____

DONOR ABO _____

CROSS CLAMP DATE _____

CROSS CLAMP TIME (Military Time) _____ Time Zone _____

CONTENTS OF BOX:

CHECK ONE:

- SPLEEN VESSELS
- NODES BLOOD
- OTHER: _____

DOCUMENTATION

	Date	Time	Initial
Ice 1:			
Ice 2:			

LEFT KIDNEY **KEEP UPRIGHT**

DONATED

HUMAN ORGAN/TISSUE
for TRANSPLANT

TO (INSTITUTION): _____

CITY: _____ STATE: _____ TEL: () _____

If available, PRIMARY FLIGHT #: _____ If available, CONNECTING FLIGHT #: _____

**In case of delays or problems call UNOS Organ Center
at 1-800-292-9537 a 24 hour number.**

This shipment is made possible by an exchange of information through United Network for Organ Sharing, a charitable, non-profit organization which has no proprietary interest in this container or its contents.

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UNITED NETWORK FOR ORGAN SHARING

HANDLE WITH CARE 

BIOLOGICAL PRODUCTS—NOT RESTRICTED, PACKED IN COMPLIANCE WITH IATA PACKAGING INSTRUCTION 650 (WET ICE).

LEFT KIDNEY

UNOS ID _____ BLOOD TYPE _____

BIOHAZARD 

- This proposal can be found on pages 141-147 of the public comment document.

Proposed Changes

■ 5.1 EXTERNAL PACKAGING SPECIFICATIONS

An external transport container is defined as a: disposable shipping box, cooler or mechanical preservation machine. The transplant center or OPO must use both internal and external transport containers to package a deceased donor organ that travels outside of the recovery facility where the organ is recovered.

Proposed Changes Cont'd

■ 5.1.3 Mechanical preservation machine

- The external surface of a mechanical preservation machine must be labeled with:
 - the standardized external label distributed by the OPTN contractor, ~~or~~
 - ~~• an alternate label that contains all information included on the OPTN contractor standardized label.~~

Proposed Changes Cont'd

■ 5.3 EXTERNAL LABELING REQUIREMENTS

When a disposable shipping box or cooler is used to transport a deceased donor organ, the Host OPO must use the standardized external label distributed by the OPTN contractor. ~~When a mechanical preservation machine is used, the OPO or Transplant Center, as applicable, may use an alternative label if the label contains all of the required information.~~

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**Proposal to Change the term
“Consent” to “Authorization”
Throughout Policy when
Referring to Deceased Organ
Donation**

Background

- Currently, UNOS policy uses the term “consent” to describe the act of making an anatomical gift.
- The public associates “consent” with the medico-legal concept of “informed consent” through which physicians must give patients all the information they need to understand the risks, benefits and costs of a particular medical treatment.

- The AMA Code of Medical Ethics requires 7 criteria be met -- most of which are not part of the donation authorization process.
- In the context of organ/tissue/eye donation after death, this blending of terms leads to misunderstandings about the act of donation that could hinder our national goal of increasing organ/tissue/eye donation and transplantation.

Overview

- The OPO community proposes changing the donation terminology from “consent” to “authorization.”
- AOPO Leadership encourages and supports this terminology change in policy.
- The proposed policy changes would align policy with current practice.
- This proposal will require programming in UNetSM.

Affected Policies/Bylaws

- Policy 2.0 — Minimum Procurement Standards for OPOs
- Policy 3.3 — Acceptance Criteria
- Policy 3.5 — Allocation of Deceased Kidneys
- Policy 5.0 — Standardized Packaging, Labeling
- Policy 6.0 — Transplantation of Non-Resident Aliens
- Policy 7.0 — Data Submission Requirements
- Policy 9.0 — Release of Information to the Public

- OPTN Bylaws — Attachment III to Appendix B — Model Elements for Controlled DCD Protocols

Sample Proposed Change

- **2.1 HOST OPO.** The OPO responding to an organ donor call from a hospital is the "Host OPO" for that particular donor. The Host OPO is responsible for identifying, evaluating and maintaining the donor, obtaining ~~consent~~ authorization for the removal of organs, complying with OPTN policy throughout the donation process, and organ allocation.
- Please refer to the public comment document pages 148-161 to review all policy changes.

Members' Responsibility

- The proposed change is strictly a nomenclature change to align policy language with that currently used in the community.
- Members will not be required to change their individual policies, so no additional evaluation is necessary.
- OPOs and transplant centers will have to follow their respective procedures if they choose to make these changes in their individual policies.

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Proposal to Modify the Imminent & Eligible (I & E) Death Definitions for Data Collection

Overview

- The OPTN began collecting patient level data on all imminent and eligible deaths in January 2008.
- Data collected have been inconsistent and refining the definitions will provide better data for analysis.
- This proposal will require programming in UNetSM (it will consist of minor changes to the Online help documentation, no changes to data fields.)

Proposed Policy Changes Provide

- A list of organ specific exclusionary criteria for classifying a death as imminent, eligible or neither;
- Clearer guidelines for identifying I & E deaths; and
- Clarification of language throughout the definitions.

Background

- Inconsistent data reporting due to:
 - OPOs interpreting the definitions differently and
 - Brain death laws vary from state to state (a person may be legally dead in one state and not in another).
- “Multi-system Organ Failure” is misinterpreted.
 - MSOF is defined as failure of 3 organ systems
 - OPOs may list a person with MSOF when the organ is functioning but not transplantable (i.e. CABG, HX of disease)

Please Note...

- **These data are for reporting purposes only** and are not intended to
 - be inclusive of all actual donors (i.e. donor over 70);
 - to screen donors;
 - affect allocation or acceptance of organs.
- They do not exclude an OPO from pursuing a donor candidate whose death is not classified as “eligible.”
- The goal is to promote consistency in reporting.

Summary of Changes

Proposed Changes:

- Eliminate multi-system organ failure (MSOF) as an exclusionary criterion for classifying as “eligible”;
- Add a list of organ-specific exclusionary criteria;
- Add minimum weight 5 kg;
- Add Body Mass Index 50 kg/m^2 or less; and
- Restrict “imminent” deaths to those that would most likely be classified as “eligible” had brain death been legally declared.

Data Considered

- The Committee reviewed data regarding age, weight and BMI for the last 3 years and
- Considered the number of donors and donor yield as age and weight increases and for BMI.
- Data regarding bilirubin, liver biopsy with percentage of microvesicular fat, SGOT/AST and % glomerulosclerosis.
- Data for the match run for kidney, liver, heart and lung to assess when transplanted organs are placed.

Data Considered Cont'd

- Organ specific data regarding the number of offers made reviewed for clarification of “exhausting the list.”
- DDR data of actual donors from 2008 to establish thresholds for the criteria (i.e. weight and BMI).
- The proposed exclusionary criteria were based on data that determined where less than 1% of donors fall. Under the proposed definition, 99.6% of all recovered donors would fall within the eligible death criteria.

- Please refer to the public comment document pages 162-174 to review all policy changes.

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OPO Committee Highlights

- The Committee is currently :
 - Considering policy requirements for uncontrolled DCD (u-DCD) similar to the DCD Model Elements.
 - Evaluating and making small modifications to the label system & will provide education sessions to include living donation labeling.
 - Considering policy clarification for the “unique identifier” that can be used for tissue typing materials.